

FATE THERAPEUTICS INC

FORM 8-K (Current report filing)

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Address	3535 GENERAL ATOMICS COURT SUITE 200 SAN DIEGO, CA 92121
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): August 14, 2017

FATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-36076
(Commission
File Number)

65-1311552
(I.R.S. Employer
Identification No.)

3535 General Atomics Court, Suite 200
San Diego, CA 92121
(Address of principal executive offices, including zip code)

(858) 875-1800
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On August 14, 2017, Fate Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2017. A copy of the press release is attached as Exhibit 99.1.

The information in this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (“Exchange Act”) or otherwise subject to the liability of that section, nor shall such information be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated August 14, 2017

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 14, 2017

FATE THERAPEUTICS, INC.

By :/s/ J. Scott Wolchko

J. Scott Wolchko

President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.

99.1

Description

Press release dated August 14, 2017



Fate Therapeutics Reports Second Quarter 2017 Financial Results

First Subject Treated with FATE-NK100 in VOYAGE for Acute Myelogenous Leukemia

FDA Clears Investigational New Drug Applications for FATE-NK100 in Recurrent Ovarian Cancer and in Advanced Solid Tumors with Monoclonal Antibody Therapy

Company Convenes PROTECT Data Monitoring Committee for ProTmune™ Phase 1 Review Following Treatment of First Six Subjects

San Diego, CA – August 14, 2017 – Fate Therapeutics, Inc. (NASDAQ: FATE), a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders, today reported business highlights and financial results for the second quarter ended June 30, 2017.

“Clinical momentum across our first-in-class cellular immunotherapy programs continues to accelerate. The first subject was treated with FATE-NK100 in VOYAGE for AML, and we look forward to opening two additional clinical trials of FATE-NK100 for the treatment of multiple advanced solid tumor types including in combination with monoclonal antibody therapy,” said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. “Our productive discussions with the FDA continue regarding the advancement of our proprietary iPSC-derived cancer immunotherapy pipeline toward first-in-human studies. We currently remain on-track to file, in the first quarter of 2018, an investigational new drug application with the FDA for FT500i, a first-of-kind natural killer cell product candidate derived from a master pluripotent cell line. We are also prepared to initiate enrollment in the Phase 2 efficacy stage of PROTECT next month. Six subjects received ProTmune and we have convened the study’s data monitoring committee to review the Phase 1 data.”

Recent Highlights & Program Updates

- **Convened PROTECT Data Monitoring Committee for ProTmune™ Phase 1 Review** . The first six subjects in the Phase 1 safety stage of PROTECT received ProTmune, the Company’s next-generation cell graft for the prevention of acute graft-versus-host disease. The Company has convened the study’s data monitoring committee to seek its recommendation regarding the initiation of the Phase 2 efficacy stage. Following the committee’s Phase 1 data review, Fate Therapeutics plans to begin enrolling the randomized, controlled and blinded Phase 2 efficacy stage of PROTECT in adult subjects with hematologic malignancies undergoing matched unrelated donor transplant during the third quarter of 2017.
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- **First Subject Treated with FATE-NK100 in VOYAGE for AML** . The Company 's first-in-class adaptive memory natural killer (NK) cell product candidate , FATE-NK100, was administered to the first subject in VOYAGE, an open-label dose - escalation clinical trial for the treatment of refractory or relapsed acute myelogenous leukemia (AML). VOYAGE is evaluating the safety and the *in vivo* persistence at Day 7 and Day 14 of a single intravenous infusion of FATE-NK100 . The anti-tumor activity of FATE-NK100 as measured by rates of complete response at 42 days post-infusion and clearance of minimal residual disease is also being assessed .
 - **IND Cleared by FDA for FATE-NK100 in Ovarian Cancer** . The U.S. Food and Drug Administration (FDA) cleared an Investigational New Drug (IND) application of FATE-NK100 for the treatment of women with ovarian cancer resistant to, or recurrent on, platinum-based treatment. The study is designed to evaluate the safety and determine the maximum dose of a single infusion of FATE-NK100 when administered directly into the peritoneum in an outpatient setting. Intraperitoneal delivery of NK cells is a novel strategy intended to promote co-localization with tumor cells and maximize NK cell persistence. Other study endpoints include objective response rate at 28 days post-infusion and progression-free and overall survival.
 - **IND Cleared by FDA for FATE-NK100 in Advanced Solid Tumors**. In May 2017, the FDA cleared the Company's IND application for the clinical investigation of FATE-NK100, including in combination with monoclonal antibody therapy, in subjects with advanced solid tumor malignancies. The Company is preparing to enroll the DIMENSION study, which is designed to evaluate the safety and anti-tumor activity of FATE-NK100 in the outpatient setting across three treatment arms: as monotherapy for small cell lung cancer and hepatocellular carcinoma; in combination with trastuzumab for advanced HER2+ breast and gastric cancers; and in combination with cetuximab for advanced EGFR1+ colorectal and head and neck cancers.
 - **Showcased First-of-Kind NK Cell Cancer Immunotherapy Pipeline at 2017 ISSCR** . In June 2017, Fate Therapeutics, along with its collaborators, presented new preclinical data on the Company's proprietary induced pluripotent stem cell (iPSC) platform and its iPSC-derived cancer immunotherapy candidates at the 2017 Annual Meeting of the International Society for Stem Cell Research (ISSCR). The Company expects to file an IND with the FDA during the first quarter of 2018 for FT500i, a first-of-kind iPSC-derived NK cell product candidate for the treatment of advanced solid tumors including in combination with checkpoint inhibitors. The session also featured the Company's second iPSC-derived NK cell product candidate FT516i, which is derived from a master engineered pluripotent cell line expressing a novel high-affinity, non-cleavable CD16 (hnCD16) Fc receptor.
 - **Extended Cash Runway through Loan Amendment** . In July 2017, Fate Therapeutics amended its loan agreement with Silicon Valley Bank pursuant to which the Company repaid its existing debt obligations in full and entered into a new \$15.0 million term loan. Cash proceeds to the Company after repayment of its existing debt obligations were \$7.5 million. Under the new term loan, only payments of interest are owed through January 1, 2019, after which time the Company will repay principal plus interest in 30 monthly installments.
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Second Quarter 2017 Financial Results

- **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of June 30, 2017 were \$71.0 million compared to \$92.1 million as of December 31, 2016. The decrease was primarily driven by the Company's use of cash to fund operating activities and to service principal and interest obligations under its loan agreement with Silicon Valley Bank. This balance as of June 30, 2017 did not include \$7.5 million in cash proceeds received by the Company in July 2017 in connection with the amendment of its loan agreement with Silicon Valley Bank.
- **Total Revenue:** Revenue was \$1.0 million for the second quarter of 2017 and as well as for the comparable period in 2016. All revenue was derived from the Company's research collaboration and license agreement with Juno Therapeutics.
- **Total Operating Expenses:** Total operating expenses were \$10.6 million for the second quarter of 2017 compared to \$9.0 million for the comparable period in 2016. Operating expenses for the second quarter of 2017 included \$1.0 million of stock compensation expense, compared to \$0.8 million for the comparable period in 2016.
- **R&D Expenses:** Research and development expenses were \$7.9 million for the second quarter of 2017 compared to \$6.8 million for the comparable period in 2016. The increase in R&D expenses was primarily related to an increase in third-party service provider fees to support the clinical development of ProTmune and FATE-NK100 and the preclinical advancement of the Company's off-the-shelf iPSC-derived cellular immunotherapy programs, and in facilities costs associated with the expansion of the Company's laboratory space.
- **G&A Expenses:** General and administrative expenses were \$2.7 million for the second quarter of 2017 compared to \$2.2 million for the comparable period in 2016. The increase in G&A expenses was primarily related to an increase in intellectual property-related expenses.
- **Shares Outstanding:** Common shares outstanding as of June 30, 2017 and December 31, 2016 were 41.4 million. Preferred shares outstanding as of June 30, 2017 and December 31, 2016 were 2.82 million, each of which is convertible into five shares of common stock. All preferred shares outstanding are from the Company's sale and issuance of non-voting Class A convertible preferred stock to Redmile Group, LLC in November 2016.

Today's Conference Call and Webcast

The Company will conduct a conference call today, Monday, August 14, 2017 at 5:00 p.m. ET to review financial and operating results for the quarter ended June 30, 2017. In order to participate in the conference call, please dial 877-303-6235 (domestic) or 631-291-4837 (international) and refer to conference ID 53251051. The live webcast can be accessed under "Events & Presentations" in the Investors & Media section of the Company's website at www.fatetherapeutics.com. The archived webcast will be available on the Company's website beginning approximately two hours after the event.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. The Company's hematopoietic cell therapy pipeline is comprised of NK- and T-cell immuno-oncology programs, including off-the-shelf product candidates derived from engineered induced pluripotent cell lines, and immuno-regulatory programs, including product candidates to prevent life-threatening complications in patients undergoing hematopoietic cell transplantation and to promote immune tolerance in patients with autoimmune disease. Its adoptive cell therapy programs are based on the Company's novel *ex vivo* cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the Company's advancement of and plans related to the Company's product candidates, clinical studies, research and development programs, the Company's progress and plans for its clinical investigation of ProTmune™ and of FATE-NK100, the Company's expected product development and regulatory strategy for its iPSC-derived product candidates, the timing for initiation of the Company's planned Phase 2 stage of PROTECT and for filing of an IND for FT500i, the therapeutic potential of ProTmune and FATE-NK100, and the Company's financial condition and projected cash expenditures. These and any other forward-looking statements in this release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that results observed in prior studies, including preclinical studies of ProTmune and FATE-NK100, will not be observed in ongoing or future studies involving these product candidates, the risk of a delay in the enrollment or evaluation of subjects in any ongoing clinical studies, the risk that the Company may cease or delay preclinical or clinical development for any of its existing or future product candidates for a variety of reasons (including requirements that may be imposed by regulatory authorities and requirements for regulatory approval, difficulties or delays in subject enrollment in current and planned clinical trials, difficulties in manufacturing and supplying the Company's product candidates for clinical testing, and any adverse events or other negative results that may be observed during preclinical or clinical development), and the risk that the Company's expenditures may exceed current expectations for a variety of reasons. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the risks and uncertainties detailed in the Company's periodic filings with the Securities and Exchange Commission, including but not limited to the Company's most recently filed periodic report, and from time to time the Company's other investor communications. Fate Therapeutics is providing the information in this release as of this date and does not undertake any

obligation to update any forward-looking statements contained in this release as a result of new information, future events or otherwise.

Availability of Other Information about Fate Therapeutics, Inc.

Investors and others should note that the Company routinely communicates with investors and the public using its website (www.fatetherapeutics.com) and its investor relations website (ir.fatetherapeutics.com), including without limitation, through the posting of investor presentations, SEC filings, press releases, public conference calls and webcasts on these websites. The information posted on these websites could be deemed to be material information. As a result, investors, the media, and others interested in Fate Therapeutics are encouraged to review this information on a regular basis. The contents of the Company's website, or any other website that may be accessed from the Company's website, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
		(unaudited)		
Collaboration revenue	\$ 1,026	\$ 1,027	\$ 2,053	\$ 2,349
Operating expenses:				
Research and development	7,927	6,782	15,893	13,418
General and administrative	2,669	2,249	5,701	4,851
Total operating expenses	<u>10,596</u>	<u>9,031</u>	<u>21,594</u>	<u>18,269</u>
Loss from operations	(9,570)	(8,004)	(19,541)	(15,920)
Other income (expense):				
Interest income	137	31	248	58
Interest expense	(212)	(435)	(478)	(923)
Total other expense, net	<u>(75)</u>	<u>(404)</u>	<u>(230)</u>	<u>(865)</u>
Net loss	<u>\$ (9,645)</u>	<u>\$ (8,408)</u>	<u>\$ (19,771)</u>	<u>\$ (16,785)</u>
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net	(5)	(3)	(38)	11
Comprehensive loss	<u>\$ (9,650)</u>	<u>\$ (8,411)</u>	<u>\$ (19,809)</u>	<u>\$ (16,774)</u>
Net loss per common share, basic and diluted	<u>\$ (0.23)</u>	<u>\$ (0.29)</u>	<u>\$ (0.48)</u>	<u>\$ (0.58)</u>
Weighted-average common shares used to compute basic and diluted net loss per share	<u>41,406,367</u>	<u>28,868,464</u>	<u>41,397,398</u>	<u>28,823,127</u>

Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,063	\$ 88,609
Short-term investments	39,950	3,503
Prepaid expenses and other current assets	848	1,211
Total current assets	71,861	93,323
Long-term assets	2,091	1,725
Total assets	\$ 73,952	\$ 95,048
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,946	\$ 4,891
Long-term debt, current portion	—	8,187
Current portion of deferred revenue	2,105	2,105
Other current liabilities	1	4
Total current liabilities	8,052	15,187
Long-term debt, net of current portion	6,676	2,501
Deferred revenue	1,776	2,829
Other long-term liabilities	2,235	1,377
Stockholders' equity	55,213	73,154
Total liabilities and stockholders' equity	\$ 73,952	\$ 95,048

Contact:

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